NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order for FDA Authorized mRNA COVID-19 Vaccine Administration – Pfizer and Moderna
Revised May 12, 2021

Purpose: To meet the goal of administering FDA-authorized COVID-19 vaccines, and to protect and save lives in the COVID-19 pandemic by vaccinating persons who meet the criteria authorized by the Food and Drug Administration and recommended by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Executive Order 193, or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA through an Emergency Use Authorization (EUA) and per conditions of this order.

COVID-19 Vaccination		
Condition or Situation	**Pfizer**	**Moderna**
	Patients (recipients of vaccine), 12 years of age and older, present requesting and consent to **Pfizer-BioNTech COVID-19 Vaccine** and have legal and decisional capacity to consent to the vaccine.	Patients (recipients of vaccine), 18 years of age and older, present requesting and consent to **Moderna COVID-19 Vaccine** and have legal and decisional capacity to consent to the vaccine.
Assessment Criteria		
Assessment Criteria	**Pfizer**	**Moderna**
	Patients shall be vaccinated with Pfizer-BioNTech COVID-19 Vaccine based on: 1. the conditions of this order 2. no history of complete 2-dose COVID-19 vaccination, regardless of brand.	Patients shall be vaccinated with Moderna COVID-19 Vaccine based on: • the conditions of this order • no history of complete 2-dose COVID-19 vaccination, regardless of brand.
Plan of Care		
Actions	**Pfizer**	**Moderna**
	• **Patient Education and Data Collection** a. Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include:	• **Patient Education and Data Collection** b. Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include: i. Where, how, and when to obtain the **second** COVID-19 vaccination.

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	i. Where, how, and when to obtain the **second** COVID-19 vaccination. ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine iii. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 12 Years of Age and Older iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. Note: Providers need to assure the most current version of this document by visiting: https://www.cvdvaccine-us.com/	ii. CDC Pre-Vaccination Checklist for COVID-19 Vaccine iii. Fact Sheet for Recipients and Caregivers Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age and Older iv. Provide the V-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in V-safe. Note: Providers need to assure the most current version of this document by visiting: https://www.modernatx.com/covid19vaccine-eua/providers/
	Content Below Applies to Both Pfizer and Moderna COVID-19 Vaccines	
	3. COVID-19 Vaccination Administration Procedures a. Review Interim Clinical Considerations for Use of COVID-19 vaccines - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html b. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine. c. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.	

	d. Review *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine. e. Instruct patients with a history of allergic reactions, including severe allergic reactions, NOT related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), that these are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. Inform these patients that there are unknown risks of developing a severe allergic reaction and they will be observed for any signs of allergic reaction after vaccination. Inform patients who have a history of anaphylaxis they will be observed for 30 minutes and other people for 15 minutes. f. Instruct patients that persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to the other (e.g., mRNA-Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions. g. Review the patient-completed *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*. h. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines Information for Healthcare Providers*, instruct patients who present under the following conditions: 1. If a patient indicates they are feeling sick on the Pre-Vaccination Checklist, ask them if they have a moderate to severe illness. If patient says yes, consult the medical provider. 2. Instruct patients with bleeding disorders or who take blood thinners a. they may have increased bleeding after intramuscular injection, and b. to call their primary care provider or seek other medical care if the injection site starts bleeding after leaving the vaccination clinic and cannot be stopped by applying pressure. 3. Instruct patients who have received passive antibody therapy as a treatment for COVID-19 that COVID-19 vaccination will be deferred for at least 90 days since their last treatment as a precautionary measure to avoid interference of the antibody treatment with vaccine-induced immune responses. 4. Instruct patients with known current symptomatic SARS-CoV-2 infection their vaccine will be deferred until the patient has recovered

from the acute illness and criteria have been met for them to discontinue isolation.

5. Instruct patients who are immunocompromised regarding unknown vaccine safety and effectiveness, that the vaccine might be less effective than in someone who is immunocompetent, potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19.
6. Instruct patients who are pregnant or lactating (breastfeeding) that these conditions are not contraindications to Pfizer and Moderna COVID-19 vaccine and may choose to get vaccinated. Educate the patient that there are limited data currently available on the safety of COVID-19 vaccines in pregnant women, but studies and results are expected soon. Data demonstrate that while the absolute risk is low, pregnant women with COVID-19 have an increased risk of severe illness. Also, educate patients that there are no data available for lactating women on mRNA vaccines' effects on lactating women.
7. Instruct patients with dermal fillers that they may develop temporary swelling at or near the filler injection site, usually face or lips, after a dose of an COVID-19 vaccine. Administer vaccines to persons with injectable dermal fillers who have no contraindications to vaccination. These persons should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.

i. Consent must be obtained from the patient or the patient's legally authorized representative prior to vaccine administration per agency policy and in accordance with NC General Statute. 90-21.13 and NC General Statute 90-21.5. Consent may be obtained verbally.

4. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.
5. Vaccine Preparation and Administration:
   a. **Preparation**: Mix, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine. Refer to: https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
   b. **Pfizer BioNTech COVID-19 Vaccine Administration**: Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 12 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 21 days after first dose.

c. **Moderna COVID-19 Vaccine Administration**: Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection in the deltoid muscle of the arm to patients 18 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used. This vaccine is administered in a 2-dose series. Second doses should be scheduled at 28 days after first dose.

d. **Second dose of COVID-19 vaccine**:
   i. **Vaccine product:** Patients shall receive the second COVID-19 vaccine dose of the same brand as first administered. Also, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. See "Vaccine Administration" and "Interchangeability of COVID-19 vaccine products" headers: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
   ii. **Timing of second dose:** The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. A second dose may be given after 6 weeks after the first dose, but the patient must be counseled that only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond 6 weeks.

e. **Needle Gauge**: Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their reported weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male fewer than 130 lbs.	22–25	5/8 ** –1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs.	22–25	1-11/2"	Deltoid muscle of arm

Male 153–260 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* Alternatively, the anterolateral thigh also can be used.
** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

f. **Bleeding Risk**: Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

g. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html) for the following time periods:

i. 30 minutes:
- Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy
- Persons with a history of anaphylaxis due to any cause
- People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson) who receive a mRNA vaccine (Pfizer or Moderna) should be observed for 30 minutes following vaccination).

ii. 15 minutes: All other persons

h. **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

i. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

j. Patients vaccinated with COVID-19 vaccines not authorized in the United States: These patients require a medical consultation. No data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized in the United States after receipt of a non-FDA-authorized COVID-19 vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently

authorized in the United States may be offered revaccination with an FDA-authorized vaccine:

i. COVID-19 vaccines not authorized by FDA but authorized for emergency use by World Health Organization (WHO)
   - Patients who completed a COVID-19 vaccination series with a vaccine that has been authorized for emergency use by the (WHO) **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
   - Patients who are partially vaccinated with a COVID-19 vaccine series authorized for emergency use by WHO may be offered an FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.

ii. COVID-19 vaccines not authorized by FDA or not authorized for emergency use by WHO
   - Patients who completed or partially completed a COVID-19 vaccine series with a vaccine that is not authorized by FDA or not authorized for emergency use by WHO may be offered an FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA authorized vaccine before administering an FDA-authorized COVID-19 vaccine.

Administration of an FDA-authorized COVID-19 vaccine in these patients should comply with all conditions of use specified under the EUA for the vaccine being used.

k. **CVMS**: Document vaccine record in CVMS **within 24 hours** after vaccine administration per system guidelines found at: https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS.

l. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy.

m. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site.

n. Counsel when and how patient needs to schedule return appointment for second dose of COVID-19 vaccine, if applicable.

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Follow-up	1. Vaccinators administering COVID-19 vaccine must report the following information associated with the administration of the vaccine in accordance with each manufacturer's fact sheets for healthcare providers administering vaccine: Pfizer: https://www.cvdvaccine-us.com/ Moderna: https://www.modernatx.com/covid19vaccine-eua/providers/dosing-administration 1. Vaccine administration errors, whether associated with an adverse event or not 2. Serious adverse events (irrespective of attribution to vaccination) 3. Cases of Multisystem inflammatory syndrome in children and adults 4. Cases of COVID-19 that result in hospitalization or death Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA or "Moderna COVID- 19 Vaccine EUA" as appropriate in the report's description section. Vaccinators are required to follow the instructions in the letter issued by the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for emergency use of COVID-19 for both Pfizer-BioNTech COVID-19 Vaccine and Moderna Vaccine. Pfizer letter: https://www.fda.gov/media/144412/download Moderna letter can be found here: https://www.fda.gov/media/144636/download
Precautions for Use of this Order	i. History of an immediate allergic reaction to any other vaccine or injectable therapies not related to a component of COVID-19 vaccines. ii. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – Pfizer or Moderna) because of potential cross-reactive hypersensitivity. Consultation with an allergist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under the supervision of a health care provider experienced in the management of severe allergic reactions. iii. Patient self-reported moderate to severe acute illness. iv. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine

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	• Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. See Appendix C: Interim Clinical Considerations for use of Covid-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
Criteria or Circumstances for Notifying Medical Provider	• Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. • Patient reports a precaution for the vaccine. • Patient is unaware of the COVID vaccine that they previously received. • Patients vaccinated with COVID-19 vaccines not authorized in the US • Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order.

Approved by: _____ _____ Date Signed: _5/12/21_____

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This order is effective immediately upon signing and may be revised or revoked by the State Health Director according to his/her discretion. This order will expire upon rescission off the State of Emergency Executive Order Number 116. Legal Authority: Executive Order 193.